DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

August 17, 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2006-19

Steve J. VanRoekel, President & CEO
Ridley, Inc.
424 North Riverfront Drive
P.O. Box 8500
Mankato, Minnesota 56002-8500

Dear Mr. VanRoekel:

An inspection of Hubbard Feeds, Inc., a subsidiary of Ridley, Inc. and a medicated feed mill located at 3154 U.S. Highway 24, Beliot, Kansas conducted by a Food and Drug Administration investigator along with Kansas Department of Agriculture inspectors on June 6 – 8, 2006 found significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds, Title 21, Code of Federal Regulations, Part 225 (21 C.F.R. 225). Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of section 501(a)(2)(B) [21 U.S.C. 351(a)(2)(B)] of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your firm's continued use of the Type A, medicated article oxytetracycline in the manufacture of medicated feeds after the drug has reached its labeled expiration date causes the new animal drug oxytetracycline to be deemed unsafe within the meaning of section 512(a)(1) [21 U.S.C. § 360b(a)(1)] of the Act and adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act. In addition, this use of oxytetracycline to produce medicated feed causes the medicated feed to be unsafe under section 512(a)(2) [21 U.S.C. § 360b(a)(2)] of the Act and adulterated under section 501(a)(6) [21 U.S. C. § 351(a)(6)] of the Act.

Our investigation found deviations including, but not limited to, the following:

- Failure to investigate and implement corrective action when assay results show medicated feeds containing Amprolium 25 were not within permissible assay limits. [21 CFR 225.58(d)]
- Despite receipt of five out of six assay results for medicated feeds containing Amprolium 25 being out of specification in approximately the last 18 months, your firm continued to manufacture and distribute said feed without identifying

the cause of the out of specification test results or implementing corrective action. [21 CFR 225.58(e)]

- Failure to establish adequate procedures for the inventory control of all drugs to aid in assuring their identity, strength, quality, and purity by continuing to manufacture medicated feed with the use of the Type A, medicated article oxytetracycline after the labeled expiration date. [21 CFR 225.42(b)]

The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction, and/or notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under section 512(m)(4)(B)(ii) [21 U.S.C. § 360b(m)(4)(B)(ii)] of the Act and 21 C.F.R. 515.22(c)(2). This letter constitutes official notification under the law.

Based on the results of the June 6 – 8, 2006 inspection, evaluated together with the evidence before FDA when the Medicated Feed Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office, in writing, within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. Your response should be directed to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

John W. Thorsky
District Director
Kansas City District